REMARKS

Favorable reconsideration is respectfully requested.

The claims are 3 to 7.

The above amendment presents claim 3 as the sole dependent claim. Claim 3 is also placed in "consisting essentially of" format to more clearly point out the invention, as will be discussed below. New claim 7 is based on previous claim 2 dependent on above amended claim 3.

Applicants acknowledge a helpful telephone interview with the Examiner on June 29, 2006 in which he indicated that if the claims contained additional limitations concerning compositions which would achieve the release profile of, for example, claim 3, this might be allowable, subject to further review. However, no commitments were made.

Claims 1 to 6 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Guy et al. (U.S. 3,906,086) in combination with Kreutner et al. (U.S. 5,869,479).

This rejection is respectfully traversed.

Guy describes a time-release pharmaceutical preparation containing aspirin as the active therapeutic agent.

Efletirizine is not mentioned and, in fact, Guy is completely focused on aspirin; no other active therapeutic agent is mentioned, or suggested. There is no generic or specific teaching or suggestion found in Guy which would direct one skilled in the art to use the specific product, efletirizine, required in the present claims.

Moreover, the "consisting essentially of" terminology presently recited clearly excludes aspirin which is required by Guy.

Lastly, there is no disclosure or suggestion of the presently recited formula for determining optimum amounts of active ingredients in the respective fractions, as presently recited. The unobviousness of the feature is detailed e.g. on pages 23 and 24 of the present specification and results in optimized efficacy.

Kreutner describes a method of relieving symptoms of rhinitis comprising administration of an antihistaminic effective amount of one or more histamine H1 receptor antagonists and an amount of one or more histamine H3 receptor antagonists. Efletirizine is cited in column 2 and claim 4 as being a histamine H1 receptor antagonist among 40 other histamine H1 receptor antagonists. Moreover, in the examples, the experimental data concern loratadine and descarboethoxyloratadine only; efletirizine is not exemplified despite the fact that the Official Action refers to Example 8.

Histamine H3 receptor antagonists are excluded from the present claims by the presently recited "consisting essentially of" terminology.

The rejection is based on an improper hindsight reconstruction of the present invention by choosing from among the disclosed long lists of active ingredients in Kreutner to arrive at the inventive composition. There is no motivation from Kreutner to encourage a person of ordinary skill in the art to choose efletirizine as required in the present claims, from among the long list of Kreutner.

The rejection has taken general disclosures from Guy's time release aspirin and Kreutner's decongestant out of context and combined several non-preferred features remote from the examples therein, to arrive at the present invention.

Lastly, Kreutner fails to disclose or suggest the presently recited equation for determining optimum content of active ingredients in the respective fractions.

Claims 1 to 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sunshine et al. (U.S. 4,464,375) in combination with Kreutner.

Further, Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sunshine et al. (U.S. 4,464,375) in combination with Kreutner as applied to claims 1 to 5 above, and further in view of Guy.

These rejections are respectfully traversed.

Sunshine describes a pharmaceutical composition comprising caffeine and one or more analgesic agents or caffeine and an anti-inflammatory agent.

As correctly pointed out by the rejection, efletirizine is not mentioned in Sunshine. However, the rejection draws attention to the specific paragraph of column 16, lines 16 to 26 which discloses "when such long acting drugs are employed, it is often desirable to include an additional analgesia-enhancing amount of caffeine in the composition in sustained release form...". Efletirizine has no link with caffeine or with analgesia, so a person skilled in the art would not apply this especially focused disclosure to efletirizine.

Moreover, caffeine is excluded by the present "consisting essentially of" terminology.

Further, Sunshine also fails to disclose or suggest the formula for determining optimized amounts of active ingredients in the respective fractions.

Lastly, the rejection employs impermissible hindsight analysis to derive the present invention from Sunshine and Kreutner and Guy by picking features throughout Sunshine and Kreutner and/or Guy to reach the target of the present claims.

Accordingly, the rejections on prior art are untenable and should be withdrawn.

No further issues remaining, allowance of this application is respectfully requested.

If the Examiner has any comments or proposals for expediting prosecution, please contact undersigned at the telephone number below.

Respectfully submitted,

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